rest. Patients are treated until unacceptable toxicity or disease progression. Statistical tests to assess survival include Wilcoxon supported by Log Rank and a nonparametric analysis of covariance (Tangen and Koch, 1999 and 2000).

Results: Patient accrual of the integrated cohort was completed in March 1999. Median follow-up time is 36 months by February 2001. Analysis of the data will occur following the unblinding of TMTX-0034.

Conclusion: TMTX-0034 and TMTX-509 are two definitive Phase III trials in first-line ACC. Final results will be available at the time of the presentation.

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Comparison of 5 classifications of colorectal carcinoma

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Purpose: The New Classification has been shown to be superior to Dukes, Astler-Coller and TNM as a predictor of individual prognosis in Israeli and American CRC pts after surgery with curative intent (Cancer 86: 782–792, 1999). This study compares five classifications of CRC in a cohort of Japanese pts, after surgery with curative intent.

Methods: Retrospective study of 504 Japanese CRC pts. Minimal follow-up: 5 years after surgery with curative intent. Sources of data: Japanese cancer registry forms, inpatient and outpatient files, and departmental follow-up registers. Tumors were staged according to Dukes, TNM, Astler-Coller, Japanese Society of Colorectal Cancer (JSCCR), and the New Classification. Kaplan-Meier survival curves (disease-free, observed, and adjusted for CRC deaths only) were calculated for each classification. Statistical significance of differences among the various survival curves was assessed by Log Rank. The 5 classifications were compared by multivariate regression analysis (Cox).

Results: All 5 classifications yielded disease-free, observed, and CRC-related survival curves that were highly significant ($p < 0.0001$). JSCCR stages 3a, 3b (in which JSCCR differs from TNM) did not differ significantly in any survival parameter ($p = 0.0756$, $p = 0.1644$, $p = 0.1791$ respectively). Multivariate regression analysis identified the New Classification as the most predictive of recurrence and survival ($p < 0.0001$).

Conclusions: 1. The New Classification is a superior predictor of individual prognosis following curative resection of CRC in Japanese pts as well. 2. The JSCCR classification of stage III CRC is not superior to TNM.

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Venous invasion (V.I.) as a prognostic indicator in TNM-II colorectal carcinoma (CRC)

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Purpose: In Israeli CRC pts after surgery with curative intent, V.I. +/− has been shown to define two subsets in each Dukes and Astler-Coller stage, that differ significantly in recurrence and survival (Europ J Cancer, vol 29A, Suppl 6, p S99, 1993). This study assesses if V.I. defines two prognostically ditinct subsets among Japanese TNM-II CRC pts as well.

Methods: Retrospective study of 504 Japanese CRC pts. Minimal follow-up: 5 years after surgery with curative intent. Sources of data: Japanese cancer registry forms, inpatient and outpatient files, and departmental follow-up registers. 151 pts (30%) had TNM-II tumors; V.I. was identified in 56 (37.1%) of them. Disease-free, observed, and CRC-related survival curves (Kaplan-Meier) were calculated for TNM-II V.I.(+) and for TNM-II V.I.(−) pts, and compared for statistical significance (Breslow).

Results: V.I.(+) was associated with an increase in local/regional as well as in distant recurrence in TNM-II CRC following surgery with curative intent. Disease-free, observed, and CRC-related survival of TNM-II V.I.(+) pts were significantly worse than those of TNM-II V.I.(−) pts ($p = 0.0129$, $p = 0.0077$, $p = 0.0141$ respectively). DFS at 5 years was 93% for TNM-II V.I.(−), and 78% for TNM-II V.I.(+).

Conclusions: 1. As in Israeli pts, substaging Japanese TNM-II CRC pts by V.I. defines two patient subsets that differ significantly in recurrence and survival. 2. Consequently, it is suggested that selection of TNM-II CRC pts for adjuvant treatment could be based on the presence of V.I. 3. This method requires no sophisticated or expensive equipment or tests, and it is immediately applicable in any health-care system worldwide.

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Comparison of five methods for substaging node-positive colorectal carcinoma

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Purpose: Future developments in adjuvant modalities may require substaging of node-positive CRC that is accurately indicative of individual prognosis, and upon which choice of agents, dosage and intensity of adjuvant treatment may be based. Venous invasion (V.I.) has been shown to be a superior definer of subsets of Israeli and American node-positive CRC pts, that differ significantly in recurrence and survival (Ann Surg Oncol 6: 161–165, 1999). This study compares 5 methods for substaging node-positive CRC in a cohort of Japanese pts following surgery with curative intent.

Methods: Retrospective study of 504 Japanese CRC pts. Minimal follow-up: 5 years after surgery with curative intent. Sources of data: Japanese cancer registry forms, inpatient and outpatient files, and departmental follow-up registers. 148 pts (29.4%) had node-positive disease [epicolic/paracolic LNs (N1 by the Japanese (JSCCR) classification) in 103 pts; intermediate LNs (N2) in 41 pts; main LNs (N3) in 4 pts]. These 148 pts were substaged according to 5 methods: 1–3 versus 4 or more (TNM N1/N2); 1–4 versus 5 or more (GITSG C1/C2); Astler-Coller C1/C2; JSCCR N1/N2+3; and by V.I.+/−. Disease-free, observed, and CRC-related survival curves (Kaplan-Meier) were calculated for each method, and compared for statistical significance (Breslow).

Results: Substaging by TNM N1/N2, GITSG C1/C2, and V.I.+/− defined subsets that differed significantly in disease-free, observed, and CRC-related survival. Substaging by Astler-Coller C1/C2, and JSCCR N1/N2+3 was not statistically significant ($p = 0.6079$, $p = 0.1171$, $p = 0.0996$; and $p = 0.0845$, $p = 0.2000$, $p = 0.2513$ respectively).

Conclusions: 1. Substaging node-positive CRC by V.I. was the only method that defined subsets that differed significantly in disease-free, observed, and CRC-related survival in Israeli, American and Japanese CRC pts alike. 2. This method has obvious biologic and oncologic significance, for it separates pts that have only lymphatic spread from pts that display microscopic hematogenous spread as well. 3. Consequently, we believe that V.I. is the method of choice for substaging node-positive CRC.

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Preoperative chemoradiotherapy (CHT-RDT) in locally advanced rectal cancer (RC). Preliminary results

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Objective: To assess the efficacy and toxicity of neoadjuvant ChT-RDT with 5-fluorouracil(5-FU) continuous infusion (CI) in locally advanced RC.

Materials and methods: From 4/96 to 3/2000, 90 patients (pts) with locally advanced RC (stage II y III) have been treated in a single centre with 5 days CI of 5-FU 300 mg/m2/day every week (w) concurrently with external beam RDT 45 Gy (1.8 Gy/session/5 session/w). Between the sixth and the eigth w after preoperative treatment, radical surgery was planned followed by postoperative ChT with 5-FU-Folinic Acid bolus, if there wasn't any evidence of progression disease (PD).

Results: 90 pts, 62 men and 28 women, with a median age of 62 years (20-76) were included. There were 78 resectable and 12 unresectable tumors. Stages: III, 72 pts (80%); II, 14 (15.6%); T3-T4 Nx 4 (4.4%). One evaluable patient didn't finish ChT because of an anginous pain. Grade III-IV gastrointestinal toxicity was observed in 1 pt. In 3 pts (3.3%), systemic PD was detected at the end of preoperative ChT-RDT. Surgery was performed in 89 pts: radical in 85 (96%) and palliative in 4 (4%). Surgical procedures included: anterior resection in 51 (57.3%), abdominoperineal resection in 36 (40.4%) and other procedures in 2. In 25 pts (41%) anal sphincter was spared. Pathological response rate was 70%: 14 complete response